SUBCOMMITTEE #3:
Health & Human Services

Chair, Senator Mark Leno

Senator Elaine K. Alquist
Senator John Benoit

March 19, 2009

9:30 a.m. *or*
Upon Adjournment of Session

Room 4203
(John L. Burton Hearing Room)

(Diane Van Maren)

Item	**Department**
4265	**Department of Public Health--*Selected Issues***

- AIDS Drug Assistance Program
- Therapeutic Monitoring Program
- Genetic Disease Testing Program
- Tobacco Control Program
- Capital Outlay for Viral and Rickettsial Laboratory
- Contract Positions Transitioning to State Staff Positions

PLEASE NOTE:

Only those items contained in this agenda will be discussed at this hearing. *Please* see the Senate File for dates and times of subsequent hearings.

Issues will be discussed in the order as noted in the Agenda unless otherwise directed by the Chair.

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DEPARTMENT OF PUBLIC HEALTH-- Item 4265

A. OVERALL BACKGROUND

Purpose of the Department. The Department of Public Health (DPH) delivers a broad range of public health programs. Some of these programs complement and support the activities of local health agencies in controlling environmental hazards, preventing and controlling disease, and providing health services to populations who have special needs. Others are solely state-operated programs, such as those that license health care facilities.

According to the DPH, their goals include the following:

- ✓ Promote healthy lifestyles and appropriate use of health services
- ✓ Prevent disease, disability and premature death
- ✓ Protect the public from unhealthy and unsafe environments
- ✓ Provide and ensure access to critical public health services
- ✓ Enhance public health emergency preparedness and response

The department comprises five public health centers, as well as the Health Information and Strategic Planning section, and the Public Health Emergency Preparedness Program. The five public health centers are as follows: (1) Center for Chronic Disease Prevention and Health Promotion; (2) Center for Environmental Health; (3) Center for Family Health; (4) Center for Health Care Quality; and (5) Center for Infectious Disease.

Summary of Funding for the Department of Public Health. The budget proposes expenditures of almost $3.3 billion ($348.9 million General Fund) for the DPH as noted in the Table below. Most of the funding for the programs administered by the DPH comes from a variety of federal funds, including grants and subventions for specified areas (such as water, emergency preparedness and Ryan White CARE Act funds). Many programs are also funded through the collection of fees for specified functions, such as for health facility licensing and certification activities. Several programs are funded through multiple sources, including General Fund support, federal funds and fee collections.

Of the amount appropriated, $637.7 million is for state operations and $2.647 billion is for local assistance. The 2009-10 budget reflects a decrease of $210.1 million as compared to the revised 2008-09 budget.

Summary of Expenditures for Department of Public Health	2009-10
Public Health Emergency Preparedness	**$103,230,000**
Public and Environmental Health	**$3,019,360,000**
Chronic Disease Prevention and Health Promotion	317,001,000
Infectious Disease	665,288,000
Family Health	1,686,298,000
Health Information and Strategic Planning	25,999,000
County Health Services	47,648,000
Environmental Health	277,126,000
Licensing and Certification Program	**$162,058,000**
Licensing and Certification of Facilities	151,432,000
Laboratory Field Services	10,626,000
Total Expenditures for Department of Public Health	**$3,284,648,000**
Funding Sources	
General Fund	$348,873,000
Federal Funds	$1,605,401,000
Genetic Disease Testing Fund	$115,019,000
Licensing and Certification Fund	$81,060,000
WIC Manufacturer Rebate Fund	$329,901,000
AIDS Drug Assistance Program Rebate Fund	$234,467,000
Water Security, Clean Drinking Water, Beach Protection Fund	$23,422,000
Safe Drinking Water Account	$13,641,000
Drinking Water Treatment and Research Fund	$5,088,000
Childhood Lead Poisoning Prevention Fund	$22,072,000
Birth Defects Monitoring Fund	$3,595,000
Radiation Control Fund	$25,093,000
Food Safety Fund	$6,732,000
Reimbursements	$203,572,000
Other Special Funds	$266,712,000
Total Expenditures	**$3,284,648,000**

(Discussion items begin on the next page.)

B. ISSUES FOR DISCUSSION

1. AIDS Drug Assistance Program (ADAP) *(Pages 4 through 11)*

Summary of Budget Appropriation. The Budget Act of 2009 provides an appropriation of $418.1 million (total funds) for 2009-10 for the ADAP, including expenditures for eligibility screening and Medicare Part D premiums.

The Table below compares the two fiscal years, as updated in the February 18-month budget package, and key components of the ADAP expenditures.

Component	2008-09 Current Year (Revised January)	2009-10 Budget Year	Difference
Prescription Costs	$348,630,000	$403,487,000	$54,857,000
Pharmacy Contractor—Operations	$11,495,000	$12,611,000	$1,116
Subtotal	**($360,125,000)**	**($416,098,000)**	**($55,973,000)**
Local Health Officers—Administration of Enrollment & Eligibility Screening	$1,000,000	$1,000,000	--
Medicare Part D Premiums	$1,000,000	$1,000,000	--
TOTAL EXPENDITURES	**$362,125,000**	**$418,098,000**	**$55,973,000**
General Fund	**$96,349,000**	**$96,349,000**	--
Drug Rebate Funds	**$177,330,000**	**$233,303,000**	**($55,973,000)**
Federal Funds	**$88,446,000**	**$88,446,000**	--

As noted in the Table, the 2009-10 appropriation reflects an increase of almost $56 million, or about 15 percent, from the revised current year. The Office of AIDS states this increase is primarily attributable to the following:

- Overall drug price increases, including general price increases, new antiretroviral drugs becoming available for treatment, and physicians switching clients to more expensive antiretroviral drug combinations; and
- An increase in ADAP enrollment of about 1,400 clients, for a total of over 35,500 clients. In addition, the average length a client will access ADAP in a 12-month period is about 7.44 months which is for a longer period than compared to other years. (For example, 6.9 months in 2005; and 7.2 months in 2007)

As noted in the Table above, the ADAP is funded using General Fund support, federal funds (Ryan White CARE Act--Part B grant), and the ADAP Drug Rebate Fund. An increase of almost $56 million in ADAP Drug Rebate Funds is assumed to support ADAP in 2009-10. This fund is discussed further below under the issues section.

No increases in General Fund support or federal fund (Ryan White CARE Act Funds—Part B) support are provided. The federal Part B funds are awarded to California based upon California meeting certain "Maintenance of Effort (MOE)" requirements for maintaining state

expenditures for HIV-related functions. No issues have been raised regarding California meeting its MOE requirements for the receipt of these federal funds.

Summary of ADAP Caseload. The ADAP is the payer of last resort. Individuals who have private health insurance, are eligible for Medi-Cal, or are eligible for Medicare, must access these services first, before the ADAP will provide services. The following chart provides a summary of the ADAP client enrollment.

ADAP Clients by Coverage Group (2008-09)

Coverage Group	Clients	Percent
ADAP-Only coverage	20,951	61.20 %
Medi-Cal coverage	407	1.19
Private coverage	5,351	15.65
Medicare coverage	7,475	21.87
TOTAL	**34,184**	**100 percent**

Subcommittee Discussion Issues—Three Items. The AIDS Drug Assistance Program (ADAP) is a core state-operated program and its fiscal structure is complex. As such, through trailer bill legislation enacted last year, the Legislature directed the Office of AIDS to annually provide a comprehensive ADAP Estimate Package in January and at the May Revision for budget purposes. This is the first year of this submittal to the Legislature.

Upon review of the ADAP Estimate Package, the following issues have been identified for discussion in Subcommittee:

1. Estimate Methodology—Two Methods Used by Office of AIDS. The Office of AIDS has two methods for estimating expenditures in the ADAP—"Linear Regression Model", and the "Percent Change Model". *Both models are used by the Administration to compare and analyze expenditures for budget purposes.*

The Linear Regression Model was used exclusively by the Administration from 1998 through 2006 for estimating purposes. The underlying assumption for this model is that the data closely fit a straight line and the trend increases or decreases at a fairly *consistent* rate or slope over time. If data trends increase rapidly, a Linear Regression Model would likely underestimate projected expenditures. If data trends decline considerably, a Linear Regression Model would likely overestimate projected expenditures.

Over the past few years, the federal Health Resources and Services Administration (HRSA) worked with states, including California, to develop budget forecasting tools to assist all state AIDS drug programs. Through this effort, several options were developed including a federal HRSA "Percent Change Model". This is the *second model* that is used for estimating ADAP.

Generally, the federal HRSA Percent Change Model does the following:

- Uses the previous year's expenditures for the program;
- Identifies factors that will increase or decrease the annual expenditures;

- Assigns percentage costs or savings for each factor; and
- Calculates the revised estimate.

The Office of AIDS then applies five California specific factors to this model as follows:

- Medicare Part D Costs;
- New drug costs, mainly for anti-retrovirals;
- Drug price increases, including ADAP clients who switch to more expensive drugs;
- Increased client costs; and
- Certain transaction fees

This Percent Change Model approach was first used by the Office of AIDS last year at the May Revision and is still being refined since the federal HRSA did not offer guidance in some of the underlying assumptions of the model. Therefore, the Office of AIDS states that this "Percent Change Model" is *more subjective* than the previously used "Linear Regression Model".

A. Estimate Methodology for Revised Current Year. For the revised 2008-09 budget (as of January 2009), the Office of AIDS estimated costs based on *both* models.

The Percent Change Model projected expenditures of $327.8 million (total funds), while the Linear Regression Model projected expenditures of $360.1 million (total funds), or $32.3 million (total funds) *more* than the Percent Change Model as shown in the Table below.

The Office of AIDS has opted to use the Linear Regression Model with an upper bound of the 95 percent confidence level in order to *not* underestimate the need for ADAP services. The February budget package adopted the $360.1 million (total funds) for the current year.

Revised Current Year ADAP Information—Model Comparison

Model Type	Estimated Total Funds	Compared to Budget Act 2008
Budget Act** of 2008	$330.3 million*	--
Percent Change Model	$327.8 million	-$2.5 million
Linear Regression Model—with upper bound at 95% confidence. ($32.3 million *more* than Percent Change Model)	$360.1 million	+$29.8 million

**Prior to a $7 million reduction for "budget balancing".

The Administration funded the increase of $29.8 million, or 9 percent, using AIDS Drug Rebate Funds. The Administration will likely be updating the current year at the May Revision.

B. Estimate Methodology for Budget Year. For 2009-10, the Office of AIDS also estimated costs based on *both* models.

The Percent Change Model projected expenditures of $350.8 million (total funds) and the Linear Regression Model projected expenditures of $416.1 million (total funds), or $65.3 million (total funds) more than the Percent Change Model as shown in the Table below.

The Office of AIDS has opted to use the Linear Regression Model with an upper bound of the 95 percent confidence level in order to *not* underestimate the need for ADAP services. The February budget package adopted the $416.1 million (total funds) for the budget year.

Budget Year ADAP Information—Model Comparison

Model Type	Estimated Total Funds	Compared to Revised Current Year
Revised 2008-09 Amount	$360.1 million	--
Percent Change Model ($65.3 million *less* than Linear Regression)	$350.8 million	-$9.3 million
Linear Regression Model—with upper bound at 95% confidence. ($65.3 million *more* than Percent Change.)	$416.1 million	+$56 million

The Administration funded the increase of $56 million, or 15 percent, over 2008-09 using AIDS Drug Rebate Funds. The Administration will be updating the budget year at the May Revision.

2. ADAP Rebate Fund. Drug rebates constitute a significant part of the annual ADAP budget. This special fund captures all drug rebates associated with ADAP, including both mandatory (required by law) and voluntary supplemental rebates (additional rebates negotiated with drug manufacturers).

California is a member of the ADAP Crisis Task Force, a state coalition of large ADAPs in the country, which negotiates additional rebates with drug manufactures for selected drugs. The Office of AIDS notes that supplemental rebate agreements are in place for all antiretrovirals on the formulary. Most supplemental rebate agreements include terms based on either an additional rebate percentage and/or a price freeze credit approach. which benefits the state.

The exact amount of rebates to be collected varies due to a number of factors, including changes in the federal calculation for mandatory rebates and the voluntary nature of the supplemental rebates. It should be noted that drug rebate collections from drug manufacturers are received by the Office of AIDS in a timely manner—usually 85 percent are received within 60-days of the invoice.

The Office of AIDS' ADAP Rebate Fund condition statement displays the following key aspects for 2009-10:

- Beginning Balance from Previous Year (roll over) $ 86.5 million
- New ADAP Rebate Revenue (estimated) $178.5 million
- Interest $ 6.7 million
- TOTAL Resources Available $271.7 million

- Office of AIDS Estimated Expenditure from Fund ($234.6 million)

- Remaining Reserve (estimated) **$37.1 million**

As noted above, the Office of AIDS estimate expenditures are about $56 million more than the "new" anticipated rebate revenue. Fortunately, there are unexpended rebate funds from prior years when have been rolled over. As such a prudent reserve is still available.

The Office of AIDS states that generally, for every dollar of ADAP expenditure, the program obtains 46 cents in rebates. This 46 percent level is based on an average of rebate collections which includes both "mandatory" and "supplemental" rebates.

3. Medicare Part D—Potential Implications for ADAP. California's ADAP also has complex interactions with the federal Medicare Part D drug benefit, implemented in January 2006. The ADAP is the payer of last resort and serves as a wrap-around for enrolled clients because it is cost-beneficial to the state.

ADAP provides, where appropriate, payment for client's Medicare Part D premiums, copayments, and deductibles. According to the Office of AIDS, presently there are 7,475 ADAP clients enrolled in Medicare Part D. The ADAP spends about $25 million (total funds) on these individuals which represents about 7 percent of ADAP expenditures, based on the revised 2008-09 budget of $360 million for ADAP.

The federal Centers for Medicare and Medicaid Services (CMS) contracts with Medicare Part D drug plans on an annual basis and drug benefits available under Part D plans will vary from year to year, including drug formulary adjustments, changes to client out-of-pocket costs, and plans entering and exiting the market.

According to the Office of AIDS, ADAP will experience ongoing fluctuations in Part D related costs due to the following factors:

- Annual adjustments to Medicare Part D maximum out-of-pocket costs thresholds;
- Annual adjustments to Part D plan premiums;
- ADAP client Part D plan selections (clients enrolling in high cost versus low cost plans);
- ADAP client Part D "low-income subsidy" eligibility; and
- Part D plan prescription co-payment requirements.

The Office of AIDS states that Medicare Part D costs for ADAP are monitored on a monthly basis to track costs. As the payer of last resort, ADAP provides assistance to clients when Medicare Part D assistance is limited or is not available. For example, ADAP clients in Part D can move from being eligible for "low income subsidies" within Part D to receiving a "standard benefit" to hitting a coverage gap known as the "donut hole"). As such, ADAP expenditures can vary for Part D enrollees, particularly if they hit the "donut hole" where there is a coverage gap and all eligible costs are absorbed by the ADAP.

The Office of AIDS states that more ADAP clients will go into the "donut hole" in 2009-10 and remain there as opposed to transitioning to a lower cost catastrophic coverage category. This is because federal Medicare law prohibits state ADAPs spending from

counting towards a Medicare beneficiary's true out-of-pocket costs ("TrOOP"). The federal CMS does permit state pharmaceutical assistance programs to count towards TrOOP.

If ADAP payments counted towards TrOOP, this would be a considerable cost offset to the ADAP, allowing ADAP clients to move out of the Part D "donut hole" and into Part D "catastrophic coverage" where Part D would fund costs. According to the Office of AIDS, this would reduce the state's costs *significantly.*

The Table below provides a summary of estimated Medicare clients enrolled in the ADAP and their Medicare Part D scenario.

Summary ADAP Caseload Enrolled in Medicare Part D & Their Scenario (2008-09)

Medicare Part D Scenario	Clients	Percent
Standard Benefit	1,608	21.52%
Donut Hole	1,650	22.07
Dual Eligible (with share of cost)	1,536	20.55
Dual Eligible ("no" share of cost)	2,681	35.87
TOTAL	**7,475**	**100 percent**

Background—ADAP Uses a Pharmacy Benefit Manager. The AIDS Drug Assistance Program was established in 1987 to help ensure that HIV-positive uninsured and under-insured individuals have access to drug therapies.

Beginning in 1997, California contracted with a pharmacy benefit manager (PBM) to centralize the purchase and distribution of drugs under ADAP. Presently, there are over 200 ADAP enrollment sites and over 3,000 pharmacies available to clients located throughout the state. Subcommittee staff notes that use of a state-wide PBM has been a successful endeavor and has been very cost-beneficial to the state (See University of AIDS Research Program analysis of 2004).

The state provides reimbursement for drug therapies listed on the ADAP formulary (over 180 drugs). The formulary includes antiretrovirals (about 30), opportunistic infection drugs, hypolipidemics, anti-depressants, vaccines, analgesics, and antibiotics. Since the AIDS virus can quickly mutate in response to a single drug, medical protocol calls for inclusion of at least three different anti-viral drugs for patients.

According to the Office of AIDS, ADAP served over 32,800 clients in 2007-08 and filled over 953,000 prescriptions for these clients (most recent *actual* data). Actual drug expenditures were $306.6 million of which $271.8 million was for antiretrovirals, or about 88 percent of the total expenditures.

Background—How Does the AIDS Drug Assistance Program Serve Clients? ADAP is a subsidy program for low and moderate income persons with HIV/AIDS. Under the program, eligible individuals receive drug therapies through participating local pharmacies under subcontract with the statewide contractor (i.e., the pharmacy benefit manager).

Individuals are eligible for ADAP if they:

- Are a resident of California;
- Are HIV-infected;
- Are 18 years of age or older;
- Have an adjusted federal income that does not exceed $50,000;
- Have a valid prescription from a licensed CA physician; and
- Lack private insurance that covers the medications or do not qualify for no-cost Medi-Cal.

ADAP clients with incomes between $43,320 (400 percent of poverty as of April 1, 2009) and $50,000 are charged monthly co-pays for their drug coverage. A typical client's co-payment obligation is calculated using the client's taxable income from a tax return. The client's co-payment is the lesser of (1) twice their annual state income tax liability, less funds expended by the person for health insurance premiums, or (2) the cost of the drugs.

Background—ADAP is the Payer of Last Resort. Both federal and state laws require that ADAP funds be used as the payer of last resort. As such, ADAP is used *only* after all other potential payer options are exhausted. This means that all Medicare eligible ADAP clients are required to utilize the prescription drug benefits available under the Medicare Part D Program. Persons eligible for private insurance coverage are required to access and utilize

Background—ADAP Drug Rebates (Federal and State Supplemental). Both federal and state law *require* ADAP drug manufacturer rebates to be paid in accordance with the same formula by which state Medicaid (Medi-Cal) programs are paid rebates. This formula is established by the federal CMS.

California also negotiates additional supplemental rebates under ADAP via a special national taskforce, along with eight other states. The mission of this taskforce is to secure additional rebates from eight manufacturers of anti-retroviral drugs (i.e., the most expensive and essential treatment therapies) and other HIV-related drugs.

Background—ADAP is Cost-Beneficial to the State. The ADAP is a core state program. Without ADAP assistance to obtain HIV/AIDS drugs, individuals would be forced to: (1) postpone treatment until disabled and Medi-Cal eligible, or (2) spend down their assets to qualify, increasing expenditures under Medi-Cal. According to the Administration, 50 percent of Medi-Cal costs are borne by the state, whereas only 30 percent of ADAP costs are borne by the state.

Studies consistently show that early intervention and treatment adherence with HIV/AIDS-related drugs prolongs life, minimizes related consequences of more serious illnesses, reduces more costly treatments, and increases an HIV-infected person's health and productivity.

Legislative Analyst's Office Comment. The LAO, in their health issues brief (dated February 6, 2009) notes that other states with budget shortfalls have implemented cost-cutting measures, such as capping client enrollment, eliminating drugs from formularies, modifying copayment requirements, and limiting per-patient expenditures.

The LAO also notes that cost-cutting measures in ADAP would likely increase the barriers to receiving care for some patients, potentially impacting the health of HIV/AIDS patients and

increasing the associated public health risks. As such, the LAO notes they will be reviewing options and will provide specific recommendations at the May Revision regarding any potential cost-saving measures.

Subcommittee Staff Comment. ADAP is a core state program which is cost-beneficial to the state, as noted above. California's legislatively enacted requirement to utilize a Pharmacy Benefit Manager approach to the program has facilitated the program's cost efficiency. Further, the Office of AIDS has significant authority to administer the program, including the ability to modify the ADAP formulary, contingent upon best medical practices. ADAP is an efficient program and is the payer of last resort; as such, its program integrity is critical to maintain.

It should be noted that California will be receiving additional federal Ryan White CARE Act funds which have not yet been appropriated in the Budget Act of 2009 due to timing issues with receipt of these funds. California receives a portion of these federal funds based on certain formulas. As such, it is not yet fully known how much California will definitively receive; however, it is probable that an increase of at least $3 million or so will be obtained.

These funds will be addressed in the May Revision. The Office of AIDS will also be providing the Legislature with a current-year and budget-year May Revision estimate to update caseload, expenditures and Drug Rebate Funds.

Questions. The Subcommittee has requested the Office of AIDS to respond to the following questions regarding each of the *three identified issues*.

Issue #1--Office of AIDS Estimate Methodology

1. Please provide a *brief* summary of the ADAP budget request *and* the estimating methodology.
2. What *key* data factors is the Administration tracking for ADAP?
3. Is it likely that this same methodology—Linear Regression with upper bound at 95 percent confidence level-- will be used for the May Revision, and will both the current year and budget year be updated?
4. Is it likely that California will be receiving any increases in federal Ryan White CARE Act funds? If yes, please briefly explain.

Issue #2—ADAP Rebate Fund

1. Please provide a *brief* summary regarding drug rebates under the ADAP.
2. Are ADAP Rebates—mandatory or supplemental—to remain fairly stable in 2009-10?

Issue #3—Medicare Part D Interactions with the ADAP

1. Specifically, how does the Medicare Part D drug benefit interact with ADAP?
2. What are the key cost drivers in this relationship?
3. What can be done with the concerns regarding a client's TrOOP in Medicare? Any federal update here?

2. Therapeutic Monitoring Program—Update

Summary of Budget Appropriation. The Budget Act of 2009 provides a total of $8 million (General Fund) for the Therapeutic Monitoring Program.

The purpose of this program is to provide therapeutic monitoring assays for HIV positive people who cannot otherwise afford them. Priority for funding under the program is to be given to state-funded Early Intervention Program sites. Coverage awards are to be made to counties on the basis of need. Determination of awards is to be made by the Office of AIDS dependant on availability of state funding, including ADAP Drug Rebate funds, and federal funding for the program.

In addition, state statute notes that counties and cities may cover those assays that are deemed necessary and are not covered under this state program. Communities can fund assays using their federal Ryan White CARE Act—Part A funds.

Specifically, viral load and resistance testing is done to measure the degree to which an individual's HIV has become resistant or less sensitive to anti-retroviral drugs. About 20,000 clients accessing Therapeutic Monitoring Program services are enrolled in ADAP.

Subcommittee Staff Comment and Recommendation. It is recommended to maintain this level of for the Therapeutic Monitoring Program and to monitor need on a periodic basis which is what the Office of AIDS is presently doing. It should be noted that ADAP Drug Rebate Funds can also be used for this purpose, and have been used in prior years. However, expenditure of Rebate Funds within the AIDS Drug Assistance Program is the priority.

Questions. The Subcommittee has requested the Office of AIDS to respond to the following questions.

1. Office of AIDS, Please provide a *brief* update on this program and its expenditures.

3. Genetic Disease Testing Program

Summary of Budget Appropriation. The Budget Act of 2009 appropriates a total of $115 million (Genetic Disease Testing Fund) for the Genetic Disease Testing Program. This reflects a net reduction of $4.8 million (Genetic Disease Testing Fund), as compared to the current-year.

Summary of Total Program

Category of Program	Total for 2009-10	Difference Compared to 2008-09
Newborn Screening Program	$45,698,000	($52,000)
Prenatal Screening Program	$49,035,000	$1,558,000
SUBTOTAL	**$94,733,000**	**$1,506,000**
Administration	$20,286,000	($6,268,000)
TOTAL	**$115,019,000**	**($4,762,000)**

As noted in the Table above, the Newborn Screening Program reflects a net nominal change—just a small adjustment primarily for caseload-driven adjustments.

The Prenatal Screening Program reflects a more involved series of adjustments due to implementation of Senate Bill 1555 (Speier), Statutes of 2006, which provides for "integrated screening" through the availability of "First Trimester Screening". With the addition of First Trimester Screening, women may choose to receive screening services in both trimesters, including a second ultrasound during the first trimester. The Department of Public Health (DPH) notes that combining both screens will result in "integrated screening", an approach that improves detection rates.

The DPH states that the Prenatal Screening Program expansion, as referenced, will begin phased-in implementation as of April 1, 2009. As such, the budget year reflects adjustments as shown in the Table below.

Prenatal Screening Program Detail

Program Component	Total for 2009-10	Difference Compared to 2008-09
Contract Laboratories	$5,090,000	$1,114,000
Scientific Costs	$12,981,000	$900,000
System Equipment & Maintenance	$6,485,000	($3,175,000)
Follow-Up Costs After Tests	$4,978,000	$639,000
Prenatal Diagnostic Centers	$18,191,000	$2,465,000
Resulting Reporting & Fee Collection	$1,310,000	($385,000)
Total—Local Assistance	**$49,035,000**	**$1.5 million**

The DPH states that the above program component expenditures, as noted in the Table, are based on the following three aspects to the Prenatal Screening Program, and the related expansion:

- Prenatal Tests, which provides screening of pregnant women for genetic and congenital disorders, will cost $41.53 per test and the volume of tests will increase by 66,700 for a total of about 435,000 women in 2009-2010.
- Follow up, referral, and counseling refers to pregnant women whose prenatal tests have shown positive results. This category will cost $49.74 per case, for an increase of $3.40 per case over the current-year. This caseload is estimated to increase by about 15,300 women for a total of about 100,000 women.
- Clinical Diagnostic Services refers to pregnant women with positive results needing diagnostic work-up. This category will cost $760 per case, for an increase of about $58 per case over the current-year. This caseload is estimated to increase by about 3,670 women for a total of about 24,000 women.

It should be noted that these assumptions may evolve as the DPH obtains more experience with the Prenatal Screening Program expansion over the course of the upcoming year.

In addition, the Administration is modifying a $4.2 million General Fund loan repayment schedule which was provided to the Genetic Disease Testing Program. This General Fund loan was made to the program due to a shortfall in the special fund in prior years. Previously this loan was to be repaid as of June 30, 2009. This repayment schedule has now been shifted back to June 30, 2011.

Background—What is the Genetic Disease Testing Program? The Genetic Disease Testing Program consists of two programs—the Newborn Screening Program and the Prenatal Screening Program. Both screening programs provide public education, and laboratory and diagnostic clinical services through contracts with private vendors, meeting states standards. Authorized follow-up services are also provided as part of the fee payment. *Generally*, the programs are self-supporting on fees collected from screening participants through the hospital unit, third party payers or private parties using a special fund—Genetic Disease Testing Fund.

The Newborn Screening Program provides screening of all newborns in California for genetic and congenital disorders that are preventable or remediable by early intervention. The fee paid for this screening is about $103 dollars. Where applicable, this fee is paid by the family's insurance, the Medi-Cal Program, or out-of-pocket.

The Prenatal Screening Program provides screening of pregnant women who consent to screening for serious birth defects. The fee paid for this screening is $162 dollars. Where applicable, this fee is paid by the family's insurance, the Medi-Cal Program, or out-of-pocket.

Subcommittee Staff Comment. No issues have been raised regarding the Genetic Disease Testing Program. However the DPH should provide comment regarding the expansion of the Prenatal Care Testing Program as well as the need to shift the repayment of the General Fund loan to June 30, 2011.

Questions. The Subcommittee has requested the Office of AIDS to respond to the following questions.

1. Department of Public Health, please provide a *brief* update on the implementation of the First Trimester Screening expansion within the Prenatal Screening Program, as well as *key* adjustments contained in the budget for this program.
2. Department of Public Health, please provide an update on the Genetic Disease Program's payment of the General Fund Loan.
3. Department of Public Health, are all of the Genetic Disease Testing Program fees being collected effectively? Are there any concerns with the collection or payment of the fees?

4. Augmentation for Richmond Laboratory Capital Outlay Project

Summary of Budget Appropriation. The Administration is proposing an augmentation of $3.1 million (General Fund) for the construction of modifications at the Viral and Rickettsial Disease Laboratory which is part of the DPH's Richmond Laboratory complex.

The DPH states that changes are desired for this laboratory to meet newly established guidelines for *"enhanced"* bio-safety Level III laboratories as determined by the U.S. Department of Agriculture, federal Centers for Disease Control and Prevention (CDC) and National Institutes for Health (NIH).

The DPH contends that compliance with these *"enhanced"* guidelines is essential for the safe *growing,* handling and examining of potentially high pathogenic influenza viral agents, thereby continuing the state's ability to respond quickly and control a potential outbreak of pandemic flu. In essence, the DPH states that this level of "enhanced" bio-safety is for *growing* the virus to have a clinical specimen to then compare any suspected samples.

Presently the Viral and Rickettsial Disease Laboratory meets bio-safety Level III preparedness but not the new "enhanced" level.

Subcommittee Staff Comments and Recommendation—Hold Open. The DPH submitted this request last year and it was deferred due to the fiscal crisis. Though the Budget Act of 2009 provides an appropriation of $3.1 million (General Fund) for this purpose, the Subcommittee may desire to amend this request for several reasons.

First, it is unknown at this time if federal stimulus funds are available for this purpose. The DPH is unclear on this matter and will be discussing this further with the federal Centers for Disease Control (CDC). Obtaining federal funding for this project makes sense and the DPH should be pursuing this venue aggressively.

Second, California continues to experience a decline in revenues, as recently reported by the Legislative Analyst's Office. As such, question arises as to how this expenditure corresponds with other potential priorities of the Legislature, such as direct health care services or services to other "core" health and human services programs.

As noted the "enhanced" guidelines are relatively new. According to the DPH, there presently are no states in the nation that meet "enhanced" guidelines but a few states maybe proceeding with changes, such as New York. The only laboratories presently certified to safely handle the Avian ("bird") Influenza viruses is the federal CDC laboratories located in Atlanta, Georgia; Ames, Iowa; and Fort Collins, Colorado.

The DPH states that in the event a case of Avian Influenza is suspected here in California, the general protocol is to use the federal CDC laboratories to conduct confirmatory testing.

Further, the DPH states where there have been two known instances where potential Influenza samples were sent to the federal CDC by the DPH for confirmation. *In both instances, the initial testing was conducted at the Richmond Laboratory complex with the federal CDC conducting the confirmatory analysis.*

In light of the state's fiscal situation and the availability of federal CDC "enhanced" bio-safety Level III laboratories to California for the specified purposes, it is recommended to keep this issue "open" until the May Revision.

Questions. The Subcommittee has requested the department to respond to the following questions.

1. DPH, Please provide a brief summary of the request.

5. Tobacco Control Program

Summary of Budget Appropriation. Several proposals were *excluded f*rom the February budget package "without prejudice" in order to provide for additional information and clarification. As such, these proposals would need *to be amended into* any future budget bill for inclusion in 2009-10.

Budget Request. The Department of Public Health (DPH) is requesting a *one-time only* increase of $6.8 million (Health Education Account, Cigarette and Tobacco Produce Surtax Funds) for the Tobacco Control Program.

This one-time only appropriation request would be funded using a portion of the reserves from the Health Education Account, Cigarette and Tobacco Produce Surtax Funds. Even with this appropriation, the Health Education Account would still have an overall reserve of $19.3 million. (It should be noted that a prudent reserve is necessary due to the fluctuation in these revenues.)

Of the requested increase, $4.5 million would be provided to the Media Campaign and $2.3 million for Competitive Grants. This increase would provide total funds of $20.2 million (Health Education Account) for the Media Campaign and $17.7 million (Health Education Account) for the Competitive Grants Program.

The DPH states the proposed augmentations would be used as follows:

- The Media Campaign would increase "target rating points" to a 500 per three-week flight in the top four media markets and maintain the target rating points in the remaining eight media markets.

- The Competitive Grant Program would add six to nine projects to be funded from $200,000 to $300,000 each. These projects may include, smoke-free multiunit housing, tobacco use in the movies, tobacco industry sponsorship, free tobacco product sampling, and tobacco cessation training and technical assistance services. Additionally, there are populations with high rates of smoking who would be focused on as well in an effort to reduce smoking in various population groups.

Background—The Tobacco Control Program. The purpose of this program is to decrease tobacco-related diseases and deaths in California by reducing tobacco use across the state. The program focuses on changing the broad social norm around the use of tobacco by indirectly influencing current and potential future tobacco users by creating an environment in which tobacco is less desirable (socially and legally where applicable). Specifically, the program focuses its tobacco control activities on:

- Countering pro-tobacco influences in the community by working to curb tobacco product retail advertisements and marketing practices;
- Reducing the exposure to secondhand smoke and tolerance of exposure;
- Reducing tobacco availability; and
- Promoting tobacco cessation services.

The DPH states that these strategies are achieved through a comprehensive infrastructure such as the *Media Campaign*, grassroots coalition efforts managed by non-profit community-based organizations, and projects funded by the *Competitive Grants Program*. In addition, the DPH supports an educational materials clearinghouse, training and technical assistance services, and the California Smokers' Helpline.

Background—Proposition 99 Funds. Proposition 99, the Tobacco Tax and Health Protection Act of 1988, established a surtax of 25 cents per package on cigarettes and other tobacco products, and provided a major new funding source for health education, indigent health care services, and resources programs.

Under the provisions of Proposition 99, revenues are allocated across six accounts based on specified percentages. These are: (1) Health Education Account—20 percent, (2) Hospital Services Account—35 percent, (3) Physician Services Account—10 percent, (4) Research Account—5 percent, (5) Unallocated Account—25 percent; and (6) Public Resources Account—5 percent.

Subcommittee Staff Comment and Recommendation. No issues have been raised regarding this request. Funds are available for this purpose from the reserves in the Health Education Account, and the Media Campaign and Competitive Grants Program are core components to the overall Tobacco Control Program.

It is recommended to adopt this proposal as requested by the DPH for inclusion in the next budget bill.

Questions. The Subcommittee has requested the department to respond to the following questions.

1. DPH, Please provide a *brief* summary of the request and how both the increase for the Media Campaign and the Local Lead Agencies would be used.

6. Department of Public Health—Shifts from Contracting to State Support

Summary of Budget Appropriation. Several proposals were *excluded f*rom the February budget package "without prejudice" in order to provide for additional information and clarification. As such, these proposals would need *to be amended into* any future budget bill for inclusion in 2009-10.

Within the DPH, there were four "without prejudice" proposals regarding the establishment of state civil service positions, in lieu of contracting out. A summary of these four proposals is shown in the Table below.

Summary of Proposals to Shift from Contracting to State Support

Program Area	Description	State Positions to Establish in 2009-10	Proposed 2009-10 Adjustment
Occupational Lead Program	Shifts $805,000 from external contracts to fund new state positions. State staff would maintain surveillance system, investigate cases of lead poisoning, collect fees from users of lead, and provide administrative support.	9.0	-$25,000 (Special)
Richmond Laboratory Complex	Shifts a total of $1.034 million from external contracts to provide janitorial services to fund new state positions for this function. The Richmond Laboratory complex consists of about 700,000 sq ft of space with eight laboratories and various other buildings.	23.0	--
Information Technology Division	Shifts a total of $852,000 from external contracts to fund new state positions. State staff would conduct various data processing functions, including software development, database development, and related program support.	6.0	-$95,000 (Federal)
Genetic Disease Program	Shifts $1.106 million from external contracts to fund new state positions. State staff would assist with customer service workload, including completing forms, assist with fee collection, and various accounting functions.	15.0	-$242,000 (Special)

The Department of Public Health (DPH) states that these requests are in response to recent rulings by the State Personnel Board that ruled the DPH had failed to meet its obligation to establish that there were no civil service job classifications to which it could appoint employees with the requisite expertise needed to perform the required work of the contracts in question.

Specifically, the Service Employees International Union (SEIU) challenged the DPH regarding: (1) the janitorial contract at the Richmond Laboratory; and (2) the information technology contract. Therefore, in order to respond to the State Personnel Board's ruling and to mitigate any future litigation, the DPH came forward with the above proposals to shift from the use of contractors to permanent state civil service classifications.

It should be noted that the DPH will be phasing in the state civil service positions over a period of time (i.e., from two to three years, commencing in 2008-09). In addition, no increased costs have been identified, only cost savings.

Subcommittee Staff Comment and Recommendation. These four DPH proposals appear to be consistent with the State Personnel Board's ruling and would potentially mitigate future litigation in this area. The requested staff adjustments appear reasonable and have no affect on the state's General Fund.

It is recommended to adopt these proposals as requested by the DPH for inclusion in the next budget bill.

Questions. The Subcommittee has requested the department to respond to the following questions.

1. DPH, Please provide a brief summary of the need for these requests, and a brief description of each request.
2. DPH, What are the benefits of using state civil service classifications?